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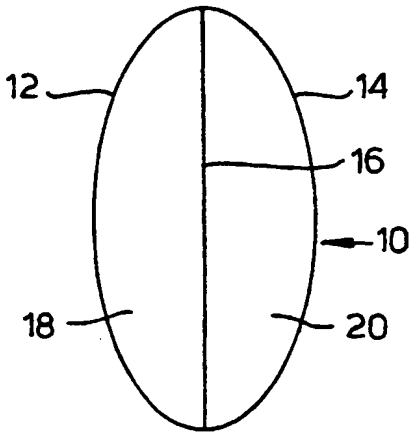
(54) Title: IMPROVEMENTS IN AND RELATING TO DELIVERY CAPSULES



(57) Abstract: A delivery capsule, designed to retain and protect its contents until an intended site of delivery or conditions of delivery are encountered, has at least two separate chambers (18, 20), the chambers usually containing different materials. The capsule is preferably internally divided by a dividing wall or septum (16), conveniently in the form of a median wall symmetrically arranged to form two chambers of similar size and shape. Also disclosed are a method of encapsulation and encapsulation apparatus.

WO 01/03676 A1

Title: Improvements in and relating to Delivery Capsules

Field of the Invention

This invention relates to a delivery capsule, that is, a capsule designed to retain and protect its contents until an intended site of delivery or conditions of delivery are encountered, at which point the capsule contents are released.

Background to the Invention

Delivery capsules are well known and find particular application in the form of ingestible gelatin capsules for the delivery of accurately metered doses of pharmaceutical preparations and dietary supplements. Liquid preparations are typically encapsulated in soft gelatin capsules and particulate or powdered preparations are typically encapsulated in two part hard gelatin capsules. The capsules are designed to release their contents after ingestion, typically by solution of the capsule wall, and by use of suitable capsule material can thus provide a means of administering a dose of a preparation at a desired appropriate site in the body. The finished capsules offer protection to the contents yet solubility within the body.

Other uses of delivery capsules include delivery of cosmetic ingredients, eg fragranced bath oils encapsulated in soft gelatin capsules for release into bath water, paint balls in the form of paint-containing capsules that rupture on impact etc.

There are limitations on current capsules and encapsulation techniques. For example, because of differences in powder and liquid handling, the processing means for the encapsulation of powders and liquids within a gelatin capsule are quite distinct and incompatible. This situation renders impossible the provision of a gelatin capsule containing both powder and liquid that are kept separate.

The present invention seeks to address certain shortcomings and limitations of current capsules and encapsulation techniques.

Summary of the Invention

In one aspect the invention provides a delivery capsule having at least two separate chambers.

The chambers of the capsule are completely discrete and separated from each other so that no communication between the chambers is possible. This means that the contents of the different chambers are kept separate from each other within the capsule until delivery.

In most cases, different chambers of the capsule will contain different materials, possibly in different physical forms, eg liquid, solid (eg tablet, particulate, powdered), slurry etc, in a way that has not hitherto been possible, although it is also possible for the different chambers to contain separate doses of the same material.

The capsule is preferably internally divided by a dividing wall or septum, conveniently in the form of a median wall symmetrically arranged to form two chambers of similar size and shape.

One or more chambers of the capsule may be further divided if required, eg by inclusion in a chamber of a smaller delivery capsule, constituting a further separate chamber.

The invention thus provides a compartmented capsule in a way that has not been done hitherto. Indeed, it is believed that this is not possible with known techniques for gelatin encapsulation.

Instead of using gelatin for encapsulation, the present invention preferably uses a heat-sealable material that is capable of deforming plastically on heating (a thermoplastic material) and/or that is capable of deforming plastically when partially solvated by

application of an appropriate solvent. Suitable materials include hydroxy propyl methyl cellulose (HPMC), pectin, polyethylene oxide, polyvinyl alcohol, alginate, polycaprolactone, gelatinised starch-based materials etc. The material may be coated, eg with gum arabic, pectin, alginate eg sodium alginate etc to modify properties. For example, gum arabic, pectin and alginate all have a slight retarding effect on HPMC solubility, the extent of the effect varying according to coating thickness. Further, both pectin and alginate can be cross-linked, eg with calcium, this has the effect of making the material pH sensitive such that it will not dissolve in the mouth but will dissolve in the stomach where pH is lower. Multi-layer materials may also be used. Examples of suitable capsule materials and coatings are given in WO 97/35537 and WO 00/27367. The capsule materials also have the advantage compared with gelatin of being non-animal derived, and so having no possibility of transmitting animal-related diseases such as bovine spongiform encepehalopathy (BSE). Such materials are commercially available, eg in the form of ribbon-like films or can be readily manufactured, eg by extrusion from solution. One currently favoured material is the thermoplastic material HPMC, in expanded or non-expanded form, with or without coatings. HPMC is suitable for ingestion by humans and so can be used for ingestible capsules as well as other uses, eg culinary, cosmetic etc.

A compartmented capsule in accordance with the invention can be used simply to keep separate in the respective chambers two materials prior to delivery. This can be of advantage, for example, when delivering to the same site two materials which react together on admixture: by use of a compartmented capsule in accordance with the invention the two materials can be kept separate until the septum wall is dissolved on delivery, bringing the materials together. This approach is also useful, say, for delivery of two separate pharmaceutical preparations. For instance, this approach is relevant to delivery of certain multi-component cold remedies which are currently unable to get FDA approval due to concerns of possible chemical reactions prior to ingestion: by using a capsule in accordance with the invention to keep the components separate within the capsule prior to delivery such difficulties can be overcome. As a further example, there is a drug called Acctuane which is an effective treatment for acne but which can also cause birth defects. In order to ensure that this does not occur birth control drugs should be

taken simultaneously with Acctuane by fertile female users. For safety reasons it would thus be far preferable if the birth control drug and the acne remedy were taken together, but kept separate until after ingestion. This can be readily achieved by use of a compartmented capsule in accordance with the invention.

Furthermore, by using different materials (either in terms of thickness and/or composition and/or coatings) defining the different chambers of the capsule, it is possible to arrange for release of the contents of the different chambers under different conditions, eg at different specific sites within the body. The contents of different compartments can thus be targeted to different specific areas within the body.

For instance, use of a thicker material defining one compartment may result in slightly delayed release of material compared with that from a compartment defined by a thinner layer of similar material.

Another example is the use of a pH sensitive coating on the material defining one chamber so that chamber contents are released at different delivery sites dependent upon pH. Use of enteric coatings such as cellulose acetate phthalate can also be used to target release, eg to within the stomach. Coatings such as ethyl cellulose can be used to retard solubility times. A further example is use of expanded HPMC defining one compartment and non-expanded HPMC defining another compartment. Expanded HPMC film releases rapidly in the mouth while standard, non-expanded film has sufficient resistance to dissolution to release only after it has been swallowed, providing that it is not kept in the mouth too long.

It is also possible to coat a finished capsule after formation with materials such as sodium alginate to improve robustness or alter solubility.

The capsule materials may include optional colourings, eg in the form of known food dyes such as FD and C yellow number 5, optional flavourings, textures etc.

The capsules may have a range of different sizes and shapes as appropriate dependent on intended usage. Capsules are typically generally spherical, ovoid, cylindrical etc in shape, preferably incorporating a median septum as described above. Typical maximum dimensions of the capsule are in the range 3mm to 20mm, but other sizes are possible.

The capsules are conveniently made by a vacuum or pressure forming technique, that may be loosely based on the technique described in WO 97/35537 but with very substantial modification.

In a further aspect, the invention thus provides a method of encapsulation, comprising supplying two films of material capable of deforming plastically on heating and/or when partially solvated; heating the films and/or applying solvent; forming the films into suitably shaped capsule portions; supplying respective substances to be encapsulated to capsule portions of each film; supplying a film of a dividing septum material to at least one of the filled capsule portions; sealing the capsule portions and septum material together to form a capsule having at least two separate chambers.

The films are preferably formed into capsule portions by application of elevated pressure or vacuum (or reduced pressure).

It is preferred to use two layers of film for producing the septum, with one film applied to each respective capsule portion, as handling including optional coating is easier.

Adhesive material is preferably applied to the various film materials to help secure the capsule portions and septum together. Capsule sealing is preferably accomplished by heat sealing, to fuse the films of material together, although other sealing methods may be used.

Pre-formed films of material may be used. Alternatively, the films may be formed during the encapsulating process, eg by being cast from solution.

In a further aspect the invention provides encapsulation apparatus, comprising means for supplying two films of material to an encapsulation unit; means for plastically deforming each film to form suitably shaped capsule portions; means for supplying respective substances to be encapsulated to the respective capsule portions of each film; means for supplying a film of dividing septum material to at least one of the filled capsule portions; and means for sealing together the capsule portions and septum material to produce a capsule having at least two separate chambers.

The apparatus typically also comprises reservoirs of the substances to be encapsulated, with associated supply arrangements adapted to supply a metered doses of the substance to the capsule portions at predetermined time intervals. The arrangement may employ syringe pumps or the like.

The apparatus conveniently includes heater means for heating the capsule film material to enable thermoplastic deformation.

The means for deforming the films conveniently comprises a pair of similar vacuum belts.

The invention is applicable to encapsulation of a wide range of pharmaceutical, culinary, cosmetic etc ingredients, enabling delivery to different sites of different materials or delivery to the same site of materials that are desirably kept separate prior to delivery.

Capsules described in this specification provide a delivery means with either at least two distinct liquid or solid, eg powder fills, or a combination of liquid and solids, eg powder. The materials can also be selected so as to exclude gelatin. The combination of materials used for the capsule wall and capsule dividing septum can be chosen to release either or both parts of the contents of capsule at specific sites within the body. These components can then address two different specific areas or act synergistically when mixed on release at the same site. In the latter example the capsule is serving to prevent the mixing of the two components prior to them reaching the correct site within the body as well as providing an accurate dose and blend of components for maximum efficacy.

The present invention enables the encapsulation of both powders and liquids within discrete chambers in an ingestible capsule. Using pre-formed rolls of film such as hydroxy propyl methyl cellulose capsules are formed with an outer shell and a dividing septum. In such a capsule two different materials which would react if brought together in a single chamber can be kept apart until the septum wall is dissolved.

By the application of surface coatings to the forming rolls and the dividing layer prior or post capsule formation, or the use of different materials for the forming rolls, capsules can be formed which release their contents under different environmental conditions. An example of this is the application to pH sensitive coatings on the outer surface of the capsule wall and septum which causes the two distinct chambers to release their contents at different delivery sites dependent upon the pH of the surrounds.

The capsules are produced on dedicated machinery employing the use of vacuum forming and heat sealing, and can be filled with liquids or powders.

The invention will be further described, by way of illustration, with reference to the accompanying drawings in which:

Figure 1 is a schematic sectional view of a delivery capsule in accordance with the invention; and

Figure 2 is a schematic representation of one embodiment of apparatus in accordance with the invention for producing a delivery capsule embodying the invention.

Detailed description of the Drawings

Referring to the drawings, Figure 1 illustrates schematically a generally ovoid delivery capsule 10 comprising at outer shell or wall in the form of two similar half shells 12 and 14 each of generally semi-ovoid form, and a median dividing wall of septum 16 that

divides the capsule into two similar chambers or compartments 18 and 20 that are completely separate from each other, with no communication between the chambers 18 and 20 being possible.

Each chamber 18 and 20 contains a metered amount of a different material (not shown), eg with a powdered or particulate material in chamber 18 and a liquid material in chamber 20, or visa versa, or with different liquid materials in each of the two chambers or with different powdered or particulate materials in each of the two chambers.

The half shells 12 and 14 of the septum 16 may be made of similar or different materials, depending on the desired properties and intended use of the capsule.

For example, where the function of the compartments is simply to keep two materials separate from each other until release at the same site of delivery, thus can be achieved by all of the capsule walls, half shells 12 and 14 and septum 16, being of the same material, eg HPMC (possibly coated as discussed above).

However, where the capsule is designed to delivery the contents of chamber 18 and chamber 20 at different sites or under different conditions, eg at different sites in the body after ingestion, it is appropriate for the capsule walls to be of different material, eg with half shell 12 of a first material and half shell 14 and septum 16 of a second, different material, with the two different materials functioning to release the contents of the associated compartment under different conditions, eg under different conditions of pH, or after different time intervals etc. For example, the first material may comprise pectin and the second material may comprise HPMC. As a further example, the first material may comprise un-coated HPMC and the second material may comprise a HPMC coated, eg with sodium alginate. Another possibility is for the first and second materials to have different coatings, eg of sodium alginate and gum arabic. A yet further possibility is for the first material to be expanded HPMC, with the second material being standard cast HPMC coated with sodium alginate.

It is also possible for septum 16 to be of completely insoluble material that will, eg, pass through the body unchanged.

The dimensions of capsule 10 may be varied to suit the intended purpose of the capsule, with the maximum dimension typically being in the range 3mm to 20mm.

Examples

The following examples serve to give specific illustrations of this invention but they are not in any way intended to limit the scope of this invention.

Example 1. A dual delivery capsule as shown in Figure 1 where the septum 16, and the capsule walls 12 and 14 are of like material, exampled by hydroxy propyl methyl cellulose.

Example 2. A dual delivery capsule as shown in Figure 1 with one wall and dividing septum of like material, exampled by hydroxy propyl methyl cellulose, and the other wall of different material, exampled by pectin.

Example 3. A dual delivery capsule as shown in Figure 1 with walls and dividing septum of like material, exampled by hydroxy propyl methyl cellulose with a coating on one half of the capsule and one side of the capsule dividing septum, exampled by sodium alginate.

Example 4. A dual delivery capsule as shown in Figure 1 with walls and dividing septum of like material, exampled by hydroxy propyl methyl cellulose with the same coating on both sides of the capsule, exampled by sodium alginate.

Example 5. A dual delivery capsule as shown in Figure 1 with walls 12 and 14 of like material exampled by hydroxy propyl methyl cellulose with different coatings on each exampled by sodium alginate and gum arabic and dividing septum 16 coated on the side closest to the wall bearing the alginate coating with gum arabic.

Example 6. A dual delivery capsule as shown in Figure 1 with a liquid fill contained in chamber 20 exampled by dextromethorphan and a powder filled example by chlopheniramine contained in chamber 18 between septum 16 and capsule wall 12.

Example 7. A dual delivery capsule as shown in Figure 1 with two different liquid fills exampled by cod liver oil and evening primrose oil contained in chamber 20 and chamber 18, respectively.

Figure 2 illustrates schematically one embodiment of apparatus for producing capsules in accordance with the invention.

The illustrated encapsulation apparatus comprises two similar, aligned, side-by-side vacuum belts 40 and 42 each comprising a plurality of articulated segments of plastics-coated aluminium as represented by segment 44. Each segment has a width of about 600mm, extending perpendicular to the plane of the sectional view of Figure 2, and is formed with a row of hemi-ovoid recesses running across its width, eg recess 46, only one such recess of each segment being visible in the drawing. Drive means (not shown) are provided for driving the two belts synchronously, with belt 40 being driven in a clockwise direction and belt 42 being driven in an anticlockwise direction, with the recesses of the two belts in registration with each other. Each recess includes a number of fine bore vacuum ports (not shown), each about 0.4mm in diameter, with vacuum means (not shown) arranged to apply a vacuum in the range -15 to -30 inches mercury. The vacuum may be applied only to the recesses in the segments when in the upper portion of travel of the belts.

Four rolls of film material 50, 52, 54 and 56 are rotatably supported on respective spindles, with the films being pulled from the spindles and over vacuum belts by a driven nip roller 58. The films pass around respective guide rollers 60, 62, 64, 66 to be brought into contact with the associated vacuum belt.

Films 50 and 52 form the generally hemi-ovoid outer shell halves of a capsule. To this end, the films pass below respective infra red heaters 68 and 70 located near the outer end of each vacuum bed, which act to heat the film passing there below to a temperature at which it is capable of deforming plastically. The films then deform to take up the shape of the recesses in the vacuum belts, assisted by the vacuum applied to the belts.

The films, moving with the vacuum bed, then pass below respective adhesive application stations 72, 74 in the form of rollers which apply adhesive to the surface of the films not within the recesses.

The films then move past respective filling stations 76, 78 where metered doses of material are supplied to each outer shell half as it passes below the station. Suitable filling equipment for supplying metered doses of liquid materials (eg syringe pumps, peristaltic pumps etc) and for supplying metered doses of powdered or particulate materials are well known. Typical volume fills are in the range 0.1 to 3.0 mls per capsule half.

The filled outer shell halves then move inwardly with the vacuum bed, past guide rollers 64, 66 around which pass lengths of septum-forming films 54, 56. The septum-forming films adhere to the non-deformed parts of films 50 and 52 under the action of the previously applied adhesive, closing off the half capsules.

The thus formed half capsules move inwardly with the vacuum belt past further adhesive stations 80, 82 which act to apply adhesive to the top surface of the septum-forming films.

The capsule halves are brought together between adjacent sides of the vacuum belts and the two septums adhere together by adhesive action. At this point, the capsules are loosely stuck together.

The films with arrays of capsules therebetween are fed to a sealing station comprising two heater blocks 88, 90 mounted on pneumatic rams that reciprocate towards and away from each other in synchronism. The blocks act to heat and fully seal together the capsule

halves, forming compartmented capsules in accordance with the invention. A knife edge (not shown) is provided on one of the blocks to cut the capsules from the remaining material. The cut capsules are collected below and the remaining film web material is passed to waste.

In a typical embodiment the films comprise HPMC having a thickness of about 120nm. Such material is readily available commercially. For example, HPMC is available from Dow Chemicals (USA) and is made into a film by Cast Film Technologies (USA).

Optional coatings may be applied to the film material, eg upstream of the rollers. Different coatings may be applied to the different half-capsule forming films.

When treating HPMC, the films should be heated at heating stations to a temperature of about 85 to 90°C so as to become thermoplastic and deformable.

A suitable adhesive for use with HPMC is HPMC with 60% propylene glycol, which can be applied warm or cold. Other possible adhesive/plasticizer materials include triacetin, monoacetin and ethyl lactate.

The adhesive formulation can also be applied before the forming heaters provided that it is of food grade and there is no reaction with the capsule contents. In such a case there will be a continuous coating of the adhesive present inside the formed capsule half. This can help with adhesion of the septum-forming film by causing a build up inside the seam.

For sealing HPMC, the heating block should be heated to a temperature in the range 150 to 170°C.

When using PVA instead of HPMC, heater temperatures must be much higher, about 150°C to produce a thermoplastic film, with the heater block typically being heated to a temperature in the range 160 to 200°C.

The illustrated equipment can run at a rate capable of producing about 30,000 capsules per hour with a web width of about 600mm.

A typical embodiment uses expanded HPMC for one capsule half and standard cast HPMC coated with sodium alginate for the other capsule half. The standard cast HPMC has a thickness of about 120 micron with a coating of alginate in the range 2 to 10 microns thick.

The application of the first adhesive is conveniently effected by rolling, extrusion or spraying, preferably by use of a roller, while application of the second adhesive is conveniently effected by a roller in contact with the film.

The capsules produced by the apparatus of Figure 2 have a form generally corresponding to the capsule of Figure 1, with septum 16 being constituted by two adhered together layers of film 54 and 56. The capsules include a short peripheral median flange (not shown in Figure 1), aligned with and extending outwardly from the position of septum 16, constituted by portions of the four films 50, 52, 54, 56 adhered together to seal the compartments and capsule.

Claims

424/45L

1. A delivery capsule having at least two separate chambers.

2. A capsule according to claim 1, wherein each chamber contains a different material.

3. A capsule according to claim 1 or 2, wherein each chamber contains a metered dose of a material.

4. A capsule according to claim 1, 2 or 3, including a dividing wall or septum defining in part two separate chambers.

5. A capsule according to claim 4, wherein the dividing wall or septum comprises two layers of material adhered together.

6. A capsule according to claim 4 or 5, wherein the dividing wall or septum comprises a median wall symmetrically arranged to form two chambers of similar size and shape.

7. A capsule according to any one of the preceding claims, formed from a heat-sealable material that is capable of deforming plastically on heating and/or when partially solvated.

8. A capsule according to claim 6, wherein the capsule is formed from one or more materials selected from hydroxy propyl methyl cellulose, pectin, polyethylene oxide, 424/45b polyvinyl alcohol, alginate, polycaprolactone, gelatinised starch based materials.

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9. A capsule according to claim 8, wherein at least part of the capsule material carries a coating.

10. A capsule according to any one of the preceding claims, wherein said at least two chambers are designed to release their contents under similar circumstances.

11. A capsule according to any one of claims 1 to 9, wherein said at least two chambers are designed to release their contents under different circumstances.

12. A capsule according to claim 11, wherein different chambers of the capsule are defined at least in part by different materials.

13. A capsule according to any one of the preceding claims, wherein the capsule is formed at least in part from hydroxy propyl methyl cellulose.

14. A capsule according to claim 13, wherein at least part of the hydroxy propyl methyl cellulose is coated with alginate.

15. A method of encapsulation comprising supplying two films of material capable of deforming plastically on heating and/or when partially solvated; heating the films and/or applying solvent; forming the films into suitably shaped capsule portions; supplying respective substances to be encapsulated to capsule portions of each film; supplying a film of a dividing septum material to at least one of the filled capsule portions; sealing the capsule portions and septum material together to form a capsule having at least two separate chambers.

16. Encapsulation apparatus comprising means for supplying two films of material to an encapsulation unit; means for plastically deforming each film to form suitably shaped capsule portions; means for supplying respective substances to be encapsulated to the respective capsule portions of each film; means for supplying a film of dividing septum material to at least one of the filled capsule portions; and means for sealing together the capsule portions and septum material to produce a capsule having at least two separate chambers.

PA NT COOPERATION TREAT

From the INTERNATIONAL BUREAU

PCT

NOTIFICATION OF THE RECORDING OF A CHANGE

(PCT Rule 92bis.1 and Administrative Instructions, Section 422)

To:

KEITH W NASH & CO
90-92 Regent Street
Cambridge CB2 1DP
ROYAUME-UNI

Date of mailing (day/month/year)
16 July 2001 (16.07.01)

Applicant's or agent's file reference
HCM/C601.01/B

IMPORTANT NOTIFICATION

International application No.
PCT/GB00/02616

International filing date (day/month/year)
07 July 2000 (07.07.00)

1. The following indications appeared on record concerning:

[X] the applicant [ ] the inventor [ ] the agent [ ] the common representative

Name and Address
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State of Residence: GB
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Facsimile No.:
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2. The International Bureau hereby notifies the applicant that the following change has been recorded concerning:

[ ] the person [ ] the name [ ] the address [X] the nationality [ ] the residence

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State of Residence: GB
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Teleprinter No.:

3. Further observations, if necessary:

4. A copy of this notification has been sent to:

[X] the receiving Office
[ ] the International Searching Authority
[X] the International Preliminary Examining Authority
[ ] the designated Offices concerned
[X] the elected Offices concerned
[ ] other:

The International Bureau of WIPO
34, chemin des Colombettes
1211 Geneva 20, Switzerland
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Authorized officer
HA Ki-Nam
Telephone No.: (41-22) 338.83.38

PA[illegible]NT COOPERATION TREAT[illegible]

From the INTERNATIONAL BUREAU

PCT

NOTIFICATION OF ELECTION

(PCT Rule 61.2)

To:

Commissioner
US Department of Commerce
United States Patent and Trademark Office, PCT
2011 South Clark Place Room
CP2/5C24
Arlington, VA 22202
ETATS-UNIS D'AMERIQUE

in its capacity as elected Office

Date of mailing (day/month/year) 13 March 2001 (13.03.01)	
International application No. PCT/GB00/02616	**Applicant's or agent's file reference** HCM/C601.01/B
International filing date (day/month/year) 07 July 2000 (07.07.00)	**Priority date** (day/month/year) 09 July 1999 (09.07.99)
Applicant NOWAK, Edward et al	

1. The designated Office is hereby notified of its election made:

[X] in the demand filed with the International Preliminary Examining Authority on:

26 January 2001 (26.01.01)

[ ] in a notice effecting later election filed with the International Bureau on:

2. The election [X] was

[ ] was not

made before the expiration of 19 months from the priority date or, where Rule 32 applies, within the time limit under Rule 32.2(b).

The International Bureau of WIPO **34, chemin des Colombettes** **1211 Geneva 20, Switzerland**	Authorized officer Pascal Piriou
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NE

PO10030902

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
HCM/C601.01/B		
International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/GB00/02616	07/07/2000	09/07/1999
International Patent Classification (IPC) or national classification and IPC A61K9/48		
Applicant BIOPROGRESS TECHNOLOGY INTERNATIONAL, INC.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 7 sheets, including this cover sheet.

   ☒ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of 2 sheets.

3. This report contains indications relating to the following items:

   - I ☒ Basis of the report
   - II ☒ Priority
   - III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - IV ☐ Lack of unity of invention
   - V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations suporting such statement
   - VI ☐ Certain documents cited
   - VII ☒ Certain defects in the international application
   - VIII ☒ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
26/01/2001	24.07.2001
Name and mailing address of the international preliminary examining authority: European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized officer Georgopoulos, N Telephone No. +49 89 2399 2634

☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):

(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

II. Priority

1. ☐ This report has been established as if no priority had been claimed due to the failure to furnish within the prescribed time limit the requested:

☐ copy of the earlier application whose priority has been claimed.

☐ translation of the earlier application whose priority has been claimed.

2. ☒ This report has been established as if no priority had been claimed due to the fact that the priority claim has been found invalid.

Thus for the purposes of this report, the international filing date indicated above is considered to be the relevant date.

3. Additional observations, if necessary:

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	6, 7, 11, 12
	No:	Claims	1-5, 8-10, 13, 14
Inventive step (IS)	Yes:	Claims	
	No:	Claims	1-14
Industrial applicability (IA)	Yes:	Claims	1-14
	No:	Claims	

2. Citations and explanations
see separate sheet

VII. Certain defects in the international application

The following defects in the form or contents of the international application have been noted:
see separate sheet

Item II

1 The priority of the present application is invalid and therefore the relevance of all P-documents cited in the International Search Report (i.e. WO-A-00 27367 and WO-A-00 28976) will be assessed as normal prior art (Rule 64 (1) PCT).

Item V

2 The amendments filed with the International Bureau under Art.19 (1) (see the letter of 26.01.01) do not contravene Art.19 (2) PCT (see the applicant's arguments in his letter of 06.07.01). The objections raised at paragraphs 1, 1.1 and 1.2 of the Written Opinion dated 18.06.01 are therefore withdrawn.

3 Reference is made to the following documents:

D1: EP-A-0 211 079

Application No Patent No	Publication date *(day/month/year)*	Filing date *(day/month/year)*	Priority date *(valid claim)* *(day/month/year)*
D2: WO-A-00 28976	25.05.00	15.11.99	16.11.98

D3: WO-A-97 35537

Application No Patent No	Publication date *(day/month/year)*	Filing date *(day/month/year)*	Priority date *(valid claim)* *(day/month/year)*
D4: WO-A-00 27367	18.05.00	04.11.99	11.11.98 and 25.10.99

4 The subject-matter of present independent claims 1, 13 and 14 as well as that of present dependent claims 2 to 5 and 8 to 10 is not new (Art.33 (2) PCT).

4.1 D1 discloses a multicellular soft capsule having an interior space defined by a shell and divided into two cells by at least one partition (see examples and claims 1 and 3 of D1). Moreover, said document discloses a method as claimed in present claim 13 (see pages 13 to 15, examples 1 to 3 and claims 9 and 10 of D1) and an encapsulation apparatus as claimed in present claim 14 (see claims 11 to 13 of D1).

It m VII

8 Contrary to the requirements of Rule 5.1 (a) (ii) PCT, the relevant background art disclosed in the documents D1 and D2 is not mentioned in the description, nor are these documents identified therein.

9 The unit of pressure "inches mercury" employed on page 10, line 7 from the bottom end is not additionally expressed in terms of the units stipulated by Rule 10.1(a) PCT.

Item VIII

10 The vague and imprecise statement "the following examples serve ... to limit the scope of this invention" in the description on page 9, lines 6 to 7 from top end of the page, implies that the subject-matter for which protection is sought may be different to that defined by the claims, thereby resulting in lack of clarity (Article 6 PCT) when used to interpret them (see also the PCT Guidelines, III - 4.3a).

10. A capsule according to claim 9, wherein different chambers of the capsule are defined at least in part by different materials.

11. A capsule according to any one of the preceding claims, wherein the capsule is formed at least in part from hydroxy propyl methyl cellulose.

12. A capsule according to claim 11, wherein at least part of the hydroxy propyl methyl cellulose is coated with alginate.

13. A method of encapsulation comprising supplying two films of material capable of deforming plastically on heating and/or when partially solvated; heating the films and/or applying solvent; forming the films into suitably shaped capsule portions; supplying respective substances to be encapsulated to capsule portions of each film; supplying a respective film of a dividing septum material to each of the filled capsule portions; sealing the capsule portions and septum material together to form a capsule having at least two separate chambers.

14. Encapsulation apparatus comprising means for supplying two films of material to an encapsulation unit; means for plastically deforming each film to form suitably shaped capsule portions; means for supplying respective substances to be encapsulated to the respective capsule portions of each film; means for supplying a respective film of dividing septum material to each of the filled capsule portions; and means for sealing together the capsule portions and septum material to produce a capsule having at least two separate chambers.

PATENT COOPERATION TREATY

From the INTERNATIONAL BUREAU

To:

KEITH W NASH & CO
90-92 Regent Street
Cambridge CB2 1DP
ROYAUME-UNI

NOTIFICATION CONCERNING SUBMISSION OR TRANSMITTAL OF PRIORITY DOCUMENT

(PCT Administrative Instructions, Section 411)

Date of mailing (day/month/year) 05 September 2000 (05.09.00)	
Applicant's or agent's file reference HCM/C601.01/B	**IMPORTANT NOTIFICATION**
International application No. PCT/GB00/02616	International filing date (day/month/year) 07 July 2000 (07.07.00)
International publication date (day/month/year) Not yet published	Priority date (day/month/year) 09 July 1999 (09.07.99)
Applicant BIOPROGRESS TECHNOLOGY INTERNATIONAL, INC. et al	

1. The applicant is hereby notified of the date of receipt (except where the letters "NR" appear in the right-hand column) by the International Bureau of the priority document(s) relating to the earlier application(s) indicated below. Unless otherwise indicated by an asterisk appearing next to a date of receipt, or by the letters "NR", in the right-hand column, the priority document concerned was submitted or transmitted to the International Bureau in compliance with Rule 17.1(a) or (b).

2. This updates and replaces any previously issued notification concerning submission or transmittal of priority documents.

3. An asterisk(*) appearing next to a date of receipt, in the right-hand column, denotes a priority document submitted or transmitted to the International Bureau but not in compliance with Rule 17.1(a) or (b). In such a case, **the attention of the applicant is directed** to Rule 17.1(c) which provides that no designated Office may disregard the priority claim concerned before giving the applicant an opportunity, upon entry into the national phase, to furnish the priority document within a time limit which is reasonable under the circumstances.

4. **The letters "NR"** appearing in the right-hand column denote a priority document which was not received by the International Bureau or which the applicant did not request the receiving Office to prepare and transmit to the International Bureau, as provided by Rule 17.1(a) or (b), respectively. In such a case, **the attention of the applicant is directed** to Rule 17.1(c) which provides that no designated Office may disregard the priority claim concerned before giving the applicant an opportunity, upon entry into the national phase, to furnish the priority document within a time limit which is reasonable under the circumstances.

Priority date	Priority application No.	Country or regional Office or PCT receiving Office	Date of receipt of priority document
09 July 1999 (09.07.99)	9916033.5	GB	10 Augu 2000 (10.08.00)

The International Bureau of WIPO
34, chemin des Colombettes
1211 Geneva 20, Switzerland

Facsimile No. (41-22) 740.14.35

Authorized officer

Lazar Joseph Panakal

Telephone No. (41-22) 338.83.38

PATENT COOPERATION TREATY

From the INTERNATIONAL BUREAU

INFORMATION CONCERNING ELECTED OFFICES NOTIFIED OF THEIR ELECTION

(PCT Rule 61.3)

To:

KEITH W NASH & CO
90-92 Regent Street
Cambridge CB2 1DP
ROYAUME-UNI

Date of mailing (day/month/year) 13 March 2001 (13.03.01)	
Applicant's or agent's file reference HCM/C601.01/B	**IMPORTANT INFORMATION**

International application No.	**International filing date** (day/month/year)	**Priority date** (day/month/year)
PCT/GB00/02616	07 July 2000 (07.07.00)	09 July 1999 (09.07.99)

Applicant
BIOPROGRESS TECHNOLOGY INTERNATIONAL, INC. et al

1. The applicant is hereby informed that the International Bureau has, according to Article 31(7), notified each of the following Offices of its election:

   AP :GH,GM,KE,LS,MW,MZ,SD,SL,SZ,TZ,UG,ZW
   EP :AT,BE,CH,CY,DE,DK,ES,FI,FR,GB,GR,IE,IT,LU,MC,NL,PT,SE
   National :AU,BG,CA,CN,CZ,DE,IL,JP,KP,KR,MN,NO,NZ,PL,RO,RU,SE,SK,US

2. The following Offices have waived the requirement for the notification of their election; the notification will be sent to them by the International Bureau only upon their request:

   EA :AM,AZ,BY,KG,KZ,MD,RU,TJ,TM
   OA :BF,BJ,CF,CG,CI,CM,GA,GN,GW,ML,MR,NE,SN,TD,TG
   National :AE,AL,AM,AT,AZ,BA,BB,BR,BY,CH,CR,CU,DK,DM,EE,ES,FI,GB,GD,GE,GH,
   GM,HR,HU,ID,IN,IS,KE,KG,KZ,LC,LK,LR,LS,LT,LU,LV,MA,MD,MG,MK,MW,MX,PT,SD,
   SG,SI,SL,TJ,TM,TR,TT,TZ,UA,UG,UZ,VN,YU,ZA,ZW

3. The applicant is reminded that he must enter the "national phase" **before the expiration of 30 months from the priority date** before each of the Offices listed above. This must be done by paying the national fee(s) and furnishing , if prescribed, a translation of the international application (Article 39(1)(a)), as well as, where applicable, by furnishing a translation of any annexes of the international preliminary examination report (Article 36(3)(b) and Rule 74.1).

   Some offices have fixed time limits expiring later than the above-mentioned time limit. For detailed information about the applicable time limits and the acts to be performed upon entry into the national phase before a particular Office, see Volume II of the PCT Applicant's Guide.

   The entry into the European regional phase is postponed **until 31 months from the priority date** for all States designated for the purposes of obtaining a European patent.

The International Bureau of WIPO
34, chemin des Colombettes
1211 Geneva 20, Switzerland

Facsimile No. (41-22) 740.14.35

Authorized officer:

Pascal Piriou

Telephone No. (41-22) 338.83.38

PATENT COOPERATION TREATY

From the INTERNATIONAL BUREAU

PCT

To:
KEITH W NASH & CO
90-92 Regent Street
Cambridge CB2 1DP
ROYAUME-UNI

NOTICE INFORMING THE APPLICANT OF THE COMMUNICATION OF THE INTERNATIONAL APPLICATION TO THE DESIGNATED OFFICES

(PCT Rule 47.1(c), first sentence)

Date of mailing (day/month/year) 18 January 2001 (18.01.01)	
Applicant's or agent's file reference HCM/C601.01/B	**IMPORTANT NOTICE**

International application No.	**International filing date** (day/month/year)	**Priority date** (day/month/year)
PCT/GB00/02616	07 July 2000 (07.07.00)	09 July 1999 (09.07.99)

Applicant
BIOPROGRESS TECHNOLOGY INTERNATIONAL, INC. et al

1. Notice is hereby given that the International Bureau has communicated, as provided in Article 20, the international application to the following designated Offices on the date indicated above as the date of mailing of this Notice:
   AU,KP,KR,US

   In accordance with Rule 47.1(c), third sentence, those Offices will accept the present Notice as conclusive evidence that the communication of the international application has duly taken place on the date of mailing indicated above and no copy of the international application is required to be furnished by the applicant to the designated Office(s).

2. The following designated Offices have waived the requirement for such a communication at this time:
   AE,AL,AM,AP,AT,AZ,BA,BB,BG,BR,BY,CA,CH,CN,CR,CU,CZ,DE,DK,DM,EA,EE,EP,ES,FI,GB,GD,
   GE,GH,GM,HR,HU,ID,IL,IN,IS,JP,KE,KG,KZ,LC,LK,LR,LS,LT,LU,LV,MA,MD,MG,MK,MN,MW,MX,
   NO,NZ,OA,PL,PT,RO,RU,SD,SE,SG,SI,SK,SL,TJ,TM,TR,TT,TZ,UA,UG,UZ,VN,YU,ZA,ZW
   The communication will be made to those Offices only upon their request. Furthermore, those Offices do not require the applicant to furnish a copy of the international application (Rule 49.1(a-bis)).

3. Enclosed with this Notice is a copy of the international application as published by the International Bureau on
   18 January 2001 (18.01.01) under No. WO 01/03676

REMINDER REGARDING CHAPTER II (Article 31(2)(a) and Rule 54.2)

If the applicant wishes to postpone entry into the national phase until 30 months (or later in some Offices) from the priority date, a demand for international preliminary examination must be filed with the competent International Preliminary Examining Authority before the expiration of 19 months from the priority date.

It is the applicant's sole responsibility to monitor the 19-month time limit.

Note that only an applicant who is a national or resident of a PCT Contracting State which is bound by Chapter II has the right to file a demand for international preliminary examination.

REMINDER REGARDING ENTRY INTO THE NATIONAL PHASE (Article 22 or 39(1))

If the applicant wishes to proceed with the international application in the national phase, he must, within 20 months or 30 months, or later in some Offices, perform the acts referred to therein before each designated or elected Office.

For further important information on the time limits and acts to be performed for entering the national phase, see the Annex to Form PCT/IB/301 (Notification of Receipt of Record Copy) and Volume II of the PCT Applicant's Guide.

The International Bureau of WIPO
34, chemin des Colombettes
1211 Geneva 20, Switzerland

Facsimile No. (41-22) 740.14.35

Authorized officer
J. Zahra

Telephone No. (41-22) 338.83.38

The demand must be filed directly with the competent International Preliminary Examining Authority or, if two or more Authorities are competent, with the one chosen by the applicant. The full name or two-letter code of that Authority may be indicated by the applicant on the line below:

IPEA/ _____

PCT

CHAPTER II

DEMAND

under Article 31 of the Patent Cooperation Treaty:
The undersigned requests that the international application specified below be the subject of international preliminary examination according to the Patent Cooperation Treaty and hereby elects all eligible States (except where otherwise indicated).

For International Preliminary Examining Authority use only

Identification of IPEA	Date of receipt of DEMAND

Box No. I IDENTIFICATION OF THE INTERNATIONAL APPLICATION

Applicant's or agent's file reference: HCM/C601.01/B

International application No.	International filing date *(day/month/year)*	(Earliest) Priority date *(day/month/year)*
PCT/GB00/02616	07.07.2000	09.07.1999

Title of invention: Improvements in or relating to delivery capsules

Box No. II APPLICANT(S)

Name and address: *(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country.)*

BioProgress Technology International, Inc.
Unit 1, Norwood Road
March
Cambridgeshire
PE15 8QD, United Kingdom

Telephone No.:

Facsimile No.:

Teleprinter No.:

State *(that is, country)* of nationality: GB

State *(that is, country)* of residence: GB

Name and address: *(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country.)*

NOWAK, Edward
4 Davey Close, Impington
Cambridge, CB4 8YJ
United Kingdom

State *(that is, country)* of nationality: GB

State *(that is, country)* of residence: GB

Name and address: *(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country.)*

MUNCASTER, Barry John
8 Burling Walk, Milton
Cambridge, CB4 6DX
United Kingdom

State *(that is, country)* of nationality: GB

State *(that is, country)* of residence: GB

[X] Further applicants are indicated on a continuation sheet.

International application No.
PCT/GB00/02616

Continuation of Box No. II APPLICANT(S)

If none of the following sub-boxes is used, this sheet should not be included in the demand.

Name and address: *(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country.)*

BROWN, Malcolm David

87 The Lammas, Mundford
Norfolk, IP26 5DS
United Kingdom

State *(that is, country)* of nationality:	State *(that is, country)* of residence:
GB	GB

Name and address: *(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country.)*

State *(that is, country)* of nationality:	State *(that is, country)* of residence:

Name and address: *(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country.)*

State *(that is, country)* of nationality:	State *(that is, country)* of residence:

Name and address: *(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country.)*

State *(that is, country)* of nationality:	State *(that is, country)* of residence:

☐ Further applicants are indicated on another continuation sheet.

International application No.
PCT/GB00/02616

Box No. III AGENT OR COMMON REPRESENTATIVE; OR ADDRESS FOR CORRESPONDENCE

The following person is [x] agent [ ] common representative

and [x] has been appointed earlier and represents the applicant(s) also for international preliminary examination.

[ ] is hereby appointed and any earlier appointment of (an) agent(s)/common representative is hereby revoked.

[ ] is hereby appointed, specifically for the procedure before the International Preliminary Examining Authority, in addition to the agent(s)/common representative appointed earlier.

Name and address: *(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country.)*

Keith w Nash & Co
90-92 Regent Street
Cambridge
CB2 1DP
United Kingdom

Telephone No.: (01223) 355477

Facsimile No.: (01223) 324353

Teleprinter No.:

[ ] **Address for correspondence:** Mark this check-box where no agent or common representative is/has been appointed and the space above is used instead to indicate a special addr ess to which correspondence should be sent.

Box No. IV BASIS FOR INTERNATIONAL PRELIMINARY EXAMINATION

Statement concerning amendments:*

1. The applicant wishes the international preliminary examination **to start on the basis of:**

[ ] the international application as originally filed

the description [ ] as originally filed
[ ] as amended under Article 34

the claims [ ] as originally filed
[x] as amended under Article 19 (together with any accompanying statement)
[ ] as amended under Article 34

the drawings [ ] as originally filed
[ ] as amended under Article 34

2. [ ] The applicant wishes any amendment to the claims under Article 19 to be considered as reversed.

3. [ ] The applicant wishes the start of the international preliminary examination **to be postponed** until the expiration of 20 months from the priority date unless the International Preliminary Examining Authority receives a copy of any amendments made under Article 19 or a notice from the applicant that he does not wish to make such amendments (Rule 69.1(d)). *(This check-box may be marked only where the time limit under Article 19 has not yet expired.)*

* Where no check-box is marked, international preliminary examination will start on the basis of the international application as originally filed or, where a copy of amendments to the claims under Article 19 and/or amendments of the international application under Article 34 are received by the International Preliminary Examining Authority before it has begun to draw up a written opinion or the international preliminary examination report, as so amended.

Language for the purposes of international preliminary examination: English

[x] which is the language in which the international application was filed.
[ ] which is the language of a translation furnished for the purposes of international search.
[ ] which is the language of publication of the international application.
[ ] which is the language of the translation (to be) furnished for the purposes of international preliminary examination.

Box No. V ELECTION OF STATES

The applicant hereby **elects all eligible States** *(that is, all States which have been designated and which are bound by Chapter II of the PCT)*

excluding the following States which the applicant wishes **not to elect:**

International application No.
PCT/GB00/02616

Box No. VI CHECK LIST

The demand is accompanied by the following elements, in the language referred to in Box No. IV, for the purposes of international preliminary examination:				For International Preliminary Examining Authority use only: received	For International Preliminary Examining Authority use only: not received
1. translation of international application	:		sheets	☐	☐
2. amendments under Article 34	:		sheets	☐	☐
3. copy (or, where required, translation) of amendments under Article 19	:	2	sheets	☐	☐
4. copy (or, where required, translation) of statement under Article 19	:		sheets	☐	☐
5. letter	:		sheets	☐	☐
6. other *(specify)*	:		sheets	☐	☐

The demand is also accompanied by the item(s) marked below:

1. ☒ fee calculation sheet
2. ☐ separate signed power of attorney
3. ☐ copy of general power of attorney; reference number, if any:
4. ☐ statement explaining lack of signature
5. ☐ nucleotide and or amino acid sequence listing in computer readable form
6. ☐ other *(specify)*:

Box No. VII SIGNATURE OF APPLICANT, AGENT OR COMMON REPRESENTATIVE

Next to each signature, indicate the name of the person signing and the capacity in which the person signs (if such capacity is not obvious from reading the demand).

Keith W Nash & Co, Agents

For International Preliminary Examining Authority use only

1. Date of actual receipt of DEMAND:
2. Adjusted date of receipt of demand due to CORRECTIONS under Rule 60.1(b):
3. ☐ The date of receipt of the demand is AFTER the expiration of 19 months from the priority date and item 4 or 5, below, does not apply. ☐ The applicant has been informed accordingly.
4. ☐ The date of receipt of the demand is WITHIN the period of 19 months from the priority date as extended by virtue of Rule 80.5.
5. ☐ Although the date of receipt of the demand is after the expiration of 19 months from the priority date, the delay in arrival is EXCUSED pursuant to Rule 82.

For International Bureau use only

Demand received from IPEA on:

See Notes to the demand form

CHAPTER II

PCT

FEE CALCULATION SHEET

Annex t the Demand for international preliminary examination

International application No. PCT/GB00/02616	For International Preliminary Examining Authority use only
Applicant's or agent's file reference HCM/C601.01/B	Date stamp of the IPEA

Applicant

BioProgress Technology International, Inc.

Calculation of prescribed fees

1. Preliminary examination fee	927.00	P
2. Handling fee *(Applicants from certain States are entitled to a reduction of 75% of the handling fee. Where the applicant is (or all applicants are) so entitled, the amount to be entered at H is 25% of the handling fee.)*	94.00	H
3. Total of prescribed fees Add the amounts entered at P and H and enter total in the TOTAL box	1021.00 TOTAL	

Mode of Payment

- [ ] authorization to charge deposit account with the IPEA (see below)
- [x] cheque
- [ ] postal money order
- [ ] bank draft
- [ ] cash
- [ ] revenue stamps
- [ ] coupons
- [ ] other *(specify)*:

Deposit Account Authorization *(this mode of payment may not be available at all IPEAs)*

The IPEA/ _____ [ ] is hereby authorized to charge the total fees indicated above to my deposit account.

[ ] *(this check-box may be marked only if the conditions for deposit accounts of the IPEA so permit)* is hereby authorized to charge any deficiency or credit any overpayment in the total fees indicated above to my deposit account.

Deposit Account Number _____ Date *(day month year)* _____ Signature _____

See Notes to the fee calculation sheet

PCT

REQUEST

The undersigned requests that the present international application be processed according to the Patent Cooperation Treaty.

For receiving Office use only

International Application No.

International Filing Date

Name of receiving Office and "PCT International Application"

Applicant's or agent's file reference *(if desired) (12 characters maximum)* HCM/C601.01/B

Box No. I TITLE OF INVENTION

Improvements in or relating to delivery capsules

Box No. II APPLICANT

Name and address: *(Family name followed by given name: for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below.)*

BioProgress Technology International, Inc.
Unit 1, Norwood Road
March
Cambridgeshire
PE15 8QD
United Kingdom

☐ This person is also inventor.

Telephone No.

Facsimile No.

Teleprinter No.

State *(that is, country)* of nationality: GB

State *(that is, country)* of residence: GB

This person is applicant for the purposes of: ☐ all designated States ☒ all designated States except the United States of America ☐ the United States of America only ☐ the States indicated in the Supplemental Box

Box No. III FURTHER APPLICANT(S) AND/OR (FURTHER) INVENTOR(S)

Name and address: *(Family name followed by given name: for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below.)*

NOWAK, Edward

4 Davey Close, Impington
Cambridge, CB4 9YJ
United Kingdom

This person is:

☐ applicant only

☒ applicant and inventor

☐ inventor only *(If this check-box is marked, do not fill in below.)*

State *(that is, country)* of nationality: GB

State *(that is, country)* of residence: GB

This person is applicant for the purposes of: ☐ all designated States ☐ all designated States except the United States of America ☒ the United States of America only ☐ the States indicated in the Supplemental Box

☒ Further applicants and/or (further) inventors are indicated on a continuation sheet.

Box No. IV AGENT OR COMMON REPRESENTATIVE; OR ADDRESS FOR CORRESPONDENCE

The person identified below is hereby/has been appointed to act on behalf of the applicant(s) before the competent International Authorities as: ☒ agent ☐ common representative

Name and address: *(Family name followed by given name: for a legal entity, full official designation. The address must include postal code and name of country.)*

Keith W Nash & Co
90-92 Regent Street
Cambridge
CB2 1DP
United Kingdom

Telephone No. (01223) 355477

Facsimile No. (01223) 324353

Teleprinter No.

☐ **Address for correspondence:** Mark this check-box where no agent or common representative is/has been appointed and the space above is used instead to indicate a special address to which correspondence should be sent.

Continuation of Box No. III FURTHER APPLICANT(S) AND/OR (FURTHER) INVENTOR(S)

If none of the following sub-boxes is used, this sheet should not be included in the request.

Name and address: *(Family name followed by given name: for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below.)*

MUNCASTER, Barry John
8 Burling Walk, Milton
Cambridge, CB4 6DX
United Kingdom

This person is:
- [ ] applicant only
- [x] applicant and inventor
- [ ] inventor only *(If this check-box is marked, do not fill in below.)*

State *(that is, country)* of nationality: GB

State *(that is, country)* of residence: GB

This person is applicant for the purposes of:
- [ ] all designated States
- [ ] all designated States except the United States of America
- [x] the United States of America only
- [ ] the States indicated in the Supplemental Box

Name and address: *(Family name followed by given name: for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below.)*

BROWN, Malcolm David
87 The Lammas, Mundford
Norfolk
IP26 5DS
United Kingdom

This person is:
- [ ] applicant only
- [x] applicant and inventor
- [ ] inventor only *(If this check-box is marked, do not fill in below.)*

State *(that is, country)* of nationality: GB

State *(that is, country)* of residence: GB

This person is applicant for the purposes of:
- [ ] all designated States
- [ ] all designated States except the United States of America
- [x] the United States of America only
- [ ] the States indicated in the Supplemental Box

Name and address: *(Family name followed by given name: for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below.)*

This person is:
- [ ] applicant only
- [ ] applicant and inventor
- [ ] inventor only *(If this check-box is marked, do not fill in below.)*

State *(that is, country)* of nationality:

State *(that is, country)* of residence:

This person is applicant for the purposes of:
- [ ] all designated States
- [ ] all designated States except the United States of America
- [ ] the United States of America only
- [ ] the States indicated in the Supplemental Box

Name and address: *(Family name followed by given name: for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below.)*

This person is:
- [ ] applicant only
- [ ] applicant and inventor
- [ ] inventor only *(If this check-box is marked, do not fill in below.)*

State *(that is, country)* of nationality:

State *(that is, country)* of residence:

This person is applicant for the purposes of:
- [ ] all designated States
- [ ] all designated States except the United States of America
- [ ] the United States of America only
- [ ] the States indicated in the Supplemental Box

- [ ] Further applicants and/or (further) inventors are indicated on another continuation sheet.

Box No.V DESIGNATION OF STATES

The following designations are hereby made under Rule 4.9(a) *(mark the applicable check-boxes; at least one must be marked)*:

Regional Patent

☒ **AP** **ARIPO Patent:** **GH** Ghana. **GM** Gambia. **KE** Kenya. **LS** Lesotho. **MW** Malawi. **SD** Sudan. **SL** Sierra Leone. **SZ** Swaziland. **TZ** United Republic of Tanzania. **UG** Uganda. **ZW** Zimbabwe. and any other State which is a Contracting State of the Harare Protocol and of the PCT

☐ **EA** **Eurasian Patent:** **AM** Armenia. **AZ** Azerbaijan. **BY** Belarus. **KG** Kyrgyzstan. **KZ** Kazakhstan. **MD** Republic of Moldova. **RU** Russian Federation. **TJ** Tajikistan. **TM** Turkmenistan. and any other State which is a Contracting State of the Eurasian Patent Convention and of the PCT

☒ **EP** **European Patent:** **AT** Austria. **BE** Belgium. **CH and LI** Switzerland and Liechtenstein. **CY** Cyprus. **DE** Germany. **DK** Denmark. **ES** Spain. **FI** Finland. **FR** France. **GB** United Kingdom. **GR** Greece. **IE** Ireland. **IT** Italy. **LU** Luxembourg. **MC** Monaco. **NL** Netherlands. **PT** Portugal. **SE** Sweden. and any other State which is a Contracting State of the European Patent Convention and of the PCT

☒ **OA** **OAPI Patent:** **BF** Burkina Faso. **BJ** Benin. **CF** Central African Republic. **CG** Congo. **CI** Côte d'Ivoire. **CM** Cameroon. **GA** Gabon. **GN** Guinea. **GW** Guinea-Bissau. **ML** Mali. **MR** Mauritania. **NE** Niger. **SN** Senegal. **TD** Chad. **TG** Togo. and any other State which is a member State of OAPI and a Contracting State of the PCT *(if other kind of protection or treatment desired, specify on dotted line)* . . . . . .

National Patent *(if other kind of protection or treatment desired, specify on dotted line)*:

☒ **AE** United Arab Emirates
☒ **AL** Albania . . . . . .
☒ **AM** Armenia . . . . . .
☒ **AT** Austria . . . . . .
☒ **AU** Australia . . . . . .
☒ **AZ** Azerbaijan
☒ **BA** Bosnia and Herzegovina . . . . . .
☒ **BB** Barbados
☒ **BG** Bulgaria . . . . . .
☒ **BR** Brazil . . . . . .
☒ **BY** Belarus . . . . . .
☒ **CA** Canada
☒ **CH and LI** Switzerland and Liechtenstein
☒ **CN** China . . . . . .
☒ **CR** Costa Rica . . . . . .
☒ **CU** Cuba . . . . . .
☒ **CZ** Czech Republic . . . . . .
☒ **DE** Germany . . . . . .
☒ **DK** Denmark . . . . . .
☒ **DM** Dominica
☒ **EE** Estonia . . . . . .
☒ **ES** Spain . . . . . .
☒ **FI** Finland . . . . . .
☒ **GB** United Kingdom
☒ **GD** Grenada
☒ **GE** Georgia . . . . . .
☒ **GH** Ghana . . . . . .
☒ **GM** Gambia
☒ **HR** Croatia . . . . . .
☒ **HU** Hungary . . . . . .
☒ **ID** Indonesia
☒ **IL** Israel . . . . . .
☒ **IN** India . . . . . .
☒ **IS** Iceland
☒ **JP** Japan . . . . . .
☒ **KE** Kenya . . . . . .
☒ **KG** Kyrgyzstan . . . . . .
☒ **KP** Democratic People's Republic of Korea . . . . . .
☒ **KR** Republic of Korea . . . . . .
☒ **KZ** Kazakhstan . . . . . .
☒ **LC** Saint Lucia
☒ **LK** Sri Lanka
☒ **LR** Liberia
☒ **LS** Lesotho . . . . . .
☒ **LT** Lithuania
☒ **LU** Luxembourg
☒ **LV** Latvia
☒ **MA** Morocco . . . . . .
☒ **MD** Republic of Moldova . . . . . .
☒ **MG** Madagascar . . . . . .
☒ **MK** The former Yugoslav Republic of Macedonia . . . . . .
☒ **MN** Mongolia
☒ **MW** Malawi . . . . . .
☒ **MX** Mexico . . . . . .
☒ **NO** Norway
☒ **NZ** New Zealand . . . . . .
☒ **PL** Poland . . . . . .
☒ **PT** Portugal . . . . . .
☒ **RO** Romania
☒ **RU** Russian Federation . . . . . .
☒ **SD** Sudan
☒ **SE** Sweden
☒ **SG** Singapore
☒ **SI** Slovenia . . . . . .
☒ **SK** Slovakia . . . . . .
☒ **SL** Sierra Leone . . . . . .
☒ **TJ** Tajikistan . . . . . .
☒ **TM** Turkmenistan . . . . . .
☒ **TR** Turkey . . . . . .
☒ **TT** Trinidad and Tobago . . . . . .
☒ **TZ** United Republic of Tanzania
☒ **UA** Ukraine . . . . . .
☒ **UG** Uganda . . . . . .
☒ **US** United States of America . . . . . .
☒ **UZ** Uzbekistan . . . . . .
☒ **VN** Viet Nam . . . . . .
☒ **YU** Yugoslavia . . . . . .
☒ **ZA** South Africa . . . . . .
☒ **ZW** Zimbabwe . . . . . .

Check-boxes reserved for designating States which have become party to the PCT after issuance of this sheet:

☐ And any new south . . . . . .
☐ . . . . . .

Precautionary Designation Statement: In addition to the designations made above, the applicant also makes under Rule 4.9(b) all other designations which would be permitted under the PCT except any designation(s) indicated in the Supplemental Box as being excluded from the scope of this statement. The applicant declares that those additional designations are subject to confirmation and that any designation which is not confirmed before the expiration of 15 months from the priority date is to be regarded as withdrawn by the applicant at the expiration of that time limit. *(Confirmation (including fees) must reach the receiving Office within the 15-month time limit.)*

Box No. VI PRIORITY CLAIM ☐ Further priority claims are indicated in the Supplemental Box.

Filing date of earlier application (day·month·year)	Number of earlier application	Where earlier application is: national application: country	regional application:* regional Office	international application: receiving Office
item (1) 09.07.1999 9th July 1999	9916033.5	GB		
item (2)				
item (3)				

☒ The receiving Office is requested to prepare and transmit to the International Bureau a certified copy of the earlier application(s) *(only if the earlier application was filed with the Office which for the purposes of the present international application is the receiving Office)* identified above as item(s): GB 9916033.5

* *Where the earlier application is an ARIPO application, it is mandatory to indicate in the Supplemental Box at least one country party to the Paris Convention for the Protection of Industrial Property for which that earlier application was filed (Rule 4.10(b)(ii)). See Supplemental Box.*

Box No. VII INTERNATIONAL SEARCHING AUTHORITY

Choice of International Searching Authority (ISA) *(if two or more International Searching Authorities are competent to carry out the international search, indicate the Authority chosen; the two-letter code may be used)*: ISA /

Request to use results of earlier search; reference to that search *(if an earlier search has been carried out by or requested from the International Searching Authority)*:

Date *(day·month·year)* Number Country *(or regional Office)*

Box No. VIII CHECK LIST; LANGUAGE OF FILING

This international application contains the following **number of sheets**:

request	:	4
description (excluding sequence listing part)	:	13
claims	:	2
abstract	:	1
drawings	:	1
sequence listing part of description	:	
Total number of sheets	:	21

This international application is **accompanied** by the item(s) marked below:

1. ☐ fee calculation sheet
2. ☐ separate signed power of attorney
3. ☐ copy of general power of attorney; reference number, if any:
4. ☐ statement explaining lack of signature
5. ☐ priority document(s) identified in Box No. VI as item(s):
6. ☐ translation of international application into (language):
7. ☐ separate indications concerning deposited microorganism or other biological material
8. ☐ nucleotide and/or amino acid sequence listing in computer readable form
9. ☐ other *(specify)*:

Figure of the drawings which should accompany the abstract: 1

Language of filing of the international application: English

Box No. IX SIGNATURE OF APPLICANT OR AGENT

Next to each signature, indicate the name of the person signing and the capacity in which the person signs (if such capacity is not obvious from reading the request).

Keith W Nash & Co, Agents

For receiving Office use only

1. Date of actual receipt of the purported international application:
2. Drawings: ☐ received: ☐ not received:
3. Corrected date of actual receipt due to later but timely received papers or drawings completing the purported international application:
4. Date of timely receipt of the required corrections under PCT Article 11(2):
5. International Searching Authority (if two or more are competent): ISA /
6. ☐ Transmittal of search copy delayed until search fee is paid.

For International Bureau use only

Date of receipt of the record copy by the International Bureau:

This sheet is not part of and does not count as a sheet of the international application.

PCT

FEE CALCULATION SHEET

Annex to the Request

For receiving Office use only

International application No.

Date stamp of the receiving Office

Applicant's or agent's file reference: HCM/C601.01/B

Applicant: BioProgress Technology International, Inc.

CALCULATION OF PRESCRIBED FEES

1. TRANSMITTAL FEE . . . . . 55.00 T

2. SEARCH FEE . . . . . 605.00 S

International search to be carried out by _____

(If two or more International Searching Authorities are competent in relation to the international application, indicate the name of the Authority which is chosen to carry out the international search.)

3. INTERNATIONAL FEE

Basic Fee

The international application contains _____ sheets.

first 30 sheets 264.00 b1

_____ (remaining sheets) x _____ (additional amount) = _____ b2

Add amounts entered at b1 and b2 and enter total at B . . . . 264.00 B

Designation Fees

The international application contains _____ designations.

8 (number of designation fees payable *(maximum 8)*) x £56 (amount of designation fee) = 448.00 D

Add amounts entered at B and D and enter total at I . . . . . 712.00 I

(Applicants from certain States are entitled to a reduction of 75% of the international fee. Where the applicant is (or all applicants are) so entitled, the total to be entered at I is 25% of the sum of the amounts entered at B and D.)

4. FEE FOR PRIORITY DOCUMENT *(if applicable)* . . . . . 22.00 P

5. TOTAL FEES PAYABLE . . . . . 1394.00 TOTAL

Add amounts entered at T, S, I and P, and enter total in the TOTAL box

☐ The designation fees are not paid at this time.

MODE OF PAYMENT

- ☐ authorization to charge deposit account (see below)
- ☒ cheque
- ☐ postal money order
- ☐ bank draft
- ☐ cash
- ☐ revenue stamps
- ☐ coupons
- ☐ other *(specify)*:

DEPOSIT ACCOUNT AUTHORIZATION *(this mode of payment may not be available at all receiving Offices)*

The RO/ _____

☐ is hereby authorized to charge the total fees indicated above to my deposit account.

☐ *(this check-box may be marked only if the conditions for deposit accounts of the receiving Office so permit)* is hereby authorized to charge any deficiency or credit any overpayment in the total fees indicated above to my deposit account.

☐ is hereby authorized to charge the fee for preparation and transmittal of the priority document to the International Bureau of WIPO to my deposit account.

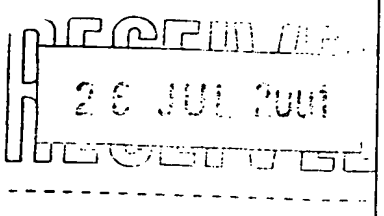
Deposit Account No. | Date *(day/month/year)* | Signature

PATENT COOPERATION TREATY

From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To:

KEITH W. NASH & CO.
90-92 Regent Street
Cambridge CB2 1DP
GRANDE BRETAGNE



PCT

NOTIFICATION OF TRANSMITTAL OF THE INTERNATIONAL PRELIMINARY EXAMINATION REPORT
(PCT Rule 71.1)

Date of mailing *(day/month/year)*	24.07.2001
Applicant's or agent's file reference HCM/C601.01/B	**IMPORTANT NOTIFICATION**

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/GB00/02616	07/07/2000	09/07/1999

Applicant
BIOPROGRESS TECHNOLOGY INTERNATIONAL, INC.

1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary examination report and its annexes, if any, established on the international application.

2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.

3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translation to those Offices.

4. **REMINDER**

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices) (Article 39(1)) (see also the reminder sent by the International Bureau with Form PCT/IB/301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary examination report. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the PCT Applicant's Guide.

Name and mailing address of the IPEA/	Authorized officer
European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Longo, E Tel.+49 89 2399-8141

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
HCM/C601.01/B		
International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/GB00/02616	07/07/2000	09/07/1999
International Patent Classification (IPC) or national classification and IPC A61K9/48		
Applicant BIOPROGRESS TECHNOLOGY INTERNATIONAL, INC.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 7 sheets, including this cover sheet.

   ☐ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of sheets.

3. This report contains indications relating to the following items:

   - I ☒ Basis of the report
   - II ☒ Priority
   - III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - IV ☐ Lack of unity of invention
   - V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations suporting such statement
   - VI ☐ Certain documents cited
   - VII ☒ Certain defects in the international application
   - VIII ☒ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
26/01/2001	24.07.2001
Name and mailing address of the international preliminary examining authority: European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized officer Georgopoulos, N Telephone No. +49 89 2399 2634

Form PCT/IPEA/409 (cover sheet) (January 1994)

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/GB00/02616

I. Basis of the report

1. With regard to the **elements** of the international application *(Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17))*:
Description, pages:

1-13 as originally filed

Claims, No.:

1-14 as amended under Article 19

Drawings, sheets:

1/1 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
- ☐ the claims, Nos.:

☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):

(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

II. Priority

1. ☐ This report has been established as if no priority had been claimed due to the failure to furnish within the prescribed time limit the requested:

☐ copy of the earlier application whose priority has been claimed.

☐ translation of the earlier application whose priority has been claimed.

2. ☒ This report has been established as if no priority had been claimed due to the fact that the priority claim has been found invalid.

Thus for the purposes of this report, the international filing date indicated above is considered to be the relevant date.

3. Additional observations, if necessary:

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	6, 7, 11, 12
	No:	Claims	1-5, 8-10, 13, 14
Inventive step (IS)	Yes:	Claims	
	No:	Claims	1-14
Industrial applicability (IA)	Yes:	Claims	1-14
	No:	Claims	

2. Citations and explanations
see separate sheet

VII. Certain defects in the international application

The following defects in the form or contents of the international application have been noted:
see separate sheet

VIII. Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:
see separate sheet

Item II

1 The priority of the present application is invalid and therefore the relevance of all P-documents cited in the International Search Report (i.e. WO-A-00 27367 and WO-A-00 28976) will be assessed as normal prior art (Rule 64 (1) PCT).

Item V

2 The amendments filed with the International Bureau under Art.19 (1) (see the letter of 26.01.01) do not contravene Art.19 (2) PCT (see the applicant's arguments in his letter of 06.07.01). The objections raised at paragraphs 1, 1.1 and 1.2 of the Written Opinion dated 18.06.01 are therefore withdrawn.

3 Reference is made to the following documents:

D1: EP-A-0 211 079

Application No Patent No	Publication date *(day/month/year)*	Filing date *(day/month/year)*	Priority date *(valid claim)* *(day/month/year)*
D2: WO-A-00 28976	25.05.00	15.11.99	16.11.98

D3: WO-A-97 35537

Application No Patent No	Publication date *(day/month/year)*	Filing date *(day/month/year)*	Priority date *(valid claim)* *(day/month/year)*
D4: WO-A-00 27367	18.05.00	04.11.99	11.11.98 and 25.10.99

4 The subject-matter of present independent claims 1, 13 and 14 as well as that of present dependent claims 2 to 5 and 8 to 10 is not new (Art.33 (2) PCT).

4.1 D1 discloses a multicellular soft capsule having an interior space defined by a shell and divided into two cells by at least one partition (see examples and claims 1 and 3 of D1). Moreover, said document discloses a method as claimed in present claim 13 (see pages 13 to 15, examples 1 to 3 and claims 9 and 10 of D1) and an encapsulation apparatus as claimed in present claim 14 (see claims 11 to 13 of D1).

Finally, D1 anticipates also the subject-matter of present dependent claims 2 (see claim 3 of D1), 3, 5 (see examples of D1), 9 and 10 (see claims 5 to 7 of D1).

D2 discloses a delivery capsule as claimed in present claim 1 (see page 12, lines 1 to 15 and claim 1 of D2), a method as claimed in present claim 13 (see claims 6 to 10 of D2) and an encapsulation apparatus as claimed in present claim 14 (see claim 11 of D2). Furthermore, the subject-matter of present dependent claims 2, 3 (see page 10, line 12 to page 11, line 2 of D2), 4 (see figures 2 and 3 of D2) and 8 (see page 3, lines 11 to 13 of D2) is anticipated by said document.

4.2 Thus, D1 anticipates the subject-matter of present claims 1 to 3, 5, 9, 10, 13 and 14 and D2 the subject-matter of present claims 1 to 4, 8, 13 and 14.

5 In contrast thereto, the subject-matter of present independent claims 1, 13 and 14 is not anticipated by any of the documents D3 or D4.

5.1 Two separate chambers as in present independent claim 1, the process steps of supplying a respective film of a dividing septum material or sealing the capsule portions and septum material together as in present claim 13 or means for supplying a respective film of a dividing septum material or sealing the capsule portions and septum material together as in present claim 14 are not mentioned in D3 or D4 (see claims 1, 4, 9, 10, 12, 13 and figure 1 of D3 and page 4, paragraph 3 to page 5, paragraph 1, page 5, paragraph 4 and claims 1 and 4 of D4).

6 Should the applicant establish novelty for present claims 1, 13 and 14, it seems that an inventive step cannot be acknowledged (Art.33 (3) PCT), as the technical problem to be solved by the present invention, namely the provision of a delivery capsule, a method for the production thereof and the respective encapsulation apparatus, wherein said capsule contains different materials which may be released under different conditions, e.g. at different specific sites within the body (see page 4, paragraph 2 of the present description) has already been solved in D1 (closest prior art document; see page 2, lines 15 to 23 of D1).

7 The subject-matter of present claims 1 to 14 is susceptible of industrial application in the field of food, pharmaceuticals and cosmetics industry (Art.33 (4) PCT).

Item VII

8 Contrary to the requirements of Rule 5.1 (a) (ii) PCT, the relevant background art disclosed in the documents D1 and D2 is not mentioned in the description, nor are these documents identified therein.

9 The unit of pressure "inches mercury" employed on page 10, line 7 from the bottom end is not additionally expressed in terms of the units stipulated by Rule 10.1(a) PCT.

Item VIII

10 The vague and imprecise statement "the following examples serve ... to limit the scope of this invention" in the description on page 9, lines 6 to 7 from top end of the page, implies that the subject-matter for which protection is sought may be different to that defined by the claims, thereby resulting in lack of clarity (Article 6 PCT) when used to interpret them (see also the PCT Guidelines, III - 4.3a).

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference	**FOR FURTHER ACTION** see Notification of Transmittal of International Search Report (Form PCT/ISA/220) as well as, where applicable, item 5 below.	
HCM/C601.01/B		
International application No.	International filing date *(day/month/year)*	(Earliest) Priority Date *(day/month/year)*
PCT/GB 00/ 02616	07/07/2000	09/07/1999
Applicant		
BIOPROGRESS TECHNOLOGY INTERNATIONAL, INC.		

This International Search Report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This International Search Report consists of a total of 3 sheets.

[X] It is also accompanied by a copy of each prior art document cited in this report.

1. **Basis of the report**

   a. With regard to the **language**, the international search was carried out on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

   [ ] the international search was carried out on the basis of a translation of the international application furnished to this Authority (Rule 23.1(b)).

   b. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international search was carried out on the basis of the sequence listing :

   [ ] contained in the international application in written form.

   [ ] filed together with the international application in computer readable form.

   [ ] furnished subsequently to this Authority in written form.

   [ ] furnished subsequently to this Authority in computer readble form.

   [ ] the statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

   [ ] the statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished

2. [ ] **Certain claims were found unsearchable** (See Box I).

3. [ ] **Unity of invention is lacking** (see Box II).

4. With regard to the **title,**

   [X] the text is approved as submitted by the applicant.

   [ ] the text has been established by this Authority to read as follows:

5. With regard to the **abstract,**

   [X] the text is approved as submitted by the applicant.

   [ ] th text has been established, according to Rul 38.2(b), by this Authority as it appears in Box III. The applicant may, within one month from th date of mailing of this international search report, submit comm nts to this Authority.

6. The figure of the **drawings** to be published with th abstract is Figure No. 1

   [X] as suggested by th applicant.

   [ ] because th applicant failed to suggest a figure.

   [ ] because this figure better charact rizes th invention.

   [ ] Non of th figures.

INTERNATIONAL SEARCH REPORT

International Application No
PC[redacted] 00/02616

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61K9/48 A61J3/07

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61K A61J

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
WPI Data, PAJ, EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	EP 0 211 079 A (FUJISAWA PHARMACEUTICAL CO., LTD.) 25 February 1987 (1987-02-25) the whole document	1-7, 10-12,16
Y	page 10, line 17 -page 11, line 5	8,9,13, 14
Y	WO 97 35537 A (BIOPROGRESS TECHNOLOGY LIMITED) 2 October 1997 (1997-10-02) cited in the application claims 1,4	8,9,13
P,Y	WO 00 27367 A (BIOPROGRESS TECHNOLOGY INTERNATIONAL INCORPORATED) 18 May 2000 (2000-05-18) cited in the application page 6, line 11 - line 17	14

-/--

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

° Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

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Date of the actual completion of the international search	Date of mailing of the international search report
11 October 2000	17/10/2000

Name and mailing address of the ISA	Authorized officer
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